

## **REMARKS**

Prior to this amendment, claims 1-34 were pending in this application. This amendment cancels claims 1-31 and 34 and amends claims 32 and 33. New claims 36-39 are added. Applicant submits that these amendments add no new matter.

### **Interview Summary**

Applicant would like to thank Examiners Burk and Marmor for their time and helpful suggestions during the in-person interview conducted on Tuesday, March 3, 2009. During that time, the Applicant, Dr. Browning, discussed those aspects of female anatomy, including the retropubic space, relevant to the claimed invention to provide clarity to the Examiners. Also, the Kovac reference was discussed as well as the claim amendments presented herein.. The Examiners agreed that because claim 33 was pending and should have been examined in the last Office action, but was not, any further Office action issued would be a non-final action.

### **Support for Claim Amendments**

Independent claim 32 has been amended to recite a method of supporting a urethra in a female adult human comprising providing a surgical tape comprising a first end, a second end, and a supporting zone interposed between the first end and the second end, wherein the tape is between about 8 to 20 cm in length. The first end of the surgical tape is fixed in the tissues of the retropubic space. The second end of the surgical tape is fixed in the tissue of the retropubic space. Support for these amendments is found in the application as originally filed, for example, at paragraphs 2, 68, 103, and 200 of the application as published.

Independent claim 33 has been amended to recite providing a first surgical tape comprising a first end and a second end, and a second surgical tape comprising a first end and a second end, wherein each of said first tape and said second tape is between about 2 to 8 cm in length. The first end of the first surgical tape is fixed in the tissues of the retropubic space and the second end is inserted into the suburethral pressure compartment. The first end of the second surgical tape is fixed in the tissues of the retropubic space and the second end is inserted into the suburethral pressure compartment. Support for these amendments is found in the application as originally filed, for example, at paragraphs 91, 93, and 200 of the application as published.

Support for new claim 36 is found in the application as originally filed, for example, at paragraph 69 of the application as published.

Support for new claim 37 is found in the application as originally filed, for example, at paragraph 94 of the application as published.

Support for new claim 38 is found in the application as originally filed, for example, at paragraph 44 of the application as published.

Support for new claim 39 is found in the application as originally filed, for example, at paragraph 45 of the application as published.

*Double Patenting Rejection*

Claim 32 is rejected on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,960,160 (“ ‘160 patent”). Applicant respectfully requests that the Examiner hold this rejection in abeyance until allowable subject matter is determined. Applicant will execute and file a terminal disclaimer similar to the draft Terminal Disclaimer attached hereto as “Exhibit A,” as necessary, to overcome the rejection.

*Claim Rejections—35 U.S.C. § 102*

***Kovac***

Claims 1-3, 14-16, 18, 24, 27, and 32 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Kovac (U.S. Patent Application Publication No. 2001/0000533, “Kovac”). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Claims 1-3, 14-16, 18, 24, and 27 have been canceled, thereby obviating these rejections. Accordingly, Applicant respectfully requests that they be reconsidered and withdrawn.

Independent claim 32, as amended, is a method for supporting a urethra in a female adult human requiring inserting the first end of the surgical tape behind a first side of the urethra and fixing said first end in the tissues of the retropubic space and inserting the second end of the surgical tape behind a second side of the urethra and fixing said second end in the tissues of the retropubic space.

Kovac teaches a pubic-bone mounted urethral stabilization and support system (Kovac, para. 14). The support system comprises a sling with an anchor attached to each end of the sling via a suture (Kovac, para. 15). The support system is inserted in a patient in the anterior vaginal wall (Kovac, para. 17) and the anchors are driven into the pubic bone and set (Kovac, para. 18). In contrast to Kovac's teaching of anchoring the ends of Kovac's device into the pubic bone, Applicant's claimed method requires fixing the first end and second end of the surgical tape in the tissues of the retropubic space.

As defined in Applicant's specification at paragraph 220 as published (U.S. Patent Application Publication No. 2006/0058578), the retropubic space is defined as "an extraperitoneal space lying *behind* the pubic bone" (emphasis added; see also para. 4, Declaration of James J. Browning, M.D., filed herewith). In other words, while the pubic bone defines a boundary of the retropubic space, the retropubic space, as well as the tissues of the retropubic space, do not include the pubic bone (see para. 4, Declaration of James J. Browning, M.D.). Accordingly, Applicant submits that Kovac fails to teach Applicant's claimed invention because anchoring the ends of Kovac's device in the pubic bone is not a teaching of fixing the ends in the tissues of the retropubic space as required by Applicant's claimed method for supporting a urethra.

In conclusion, because Kovac does not teach that the first end and the second end of Kovac's device are fixed in the retropubic space, Applicant submits that Kovac is an improper anticipatory reference. Accordingly, Applicant respectfully requests that the rejection of claim 32 in view of Kovac be reconsidered and withdrawn.

*Claim Rejections—35 U.S.C. § 103*

***Kovac and Thompson***

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Thompson (U.S. Patent No. 5,997,554, "Thompson"). Claims 4 and 5 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac and Columbus***

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Columbus (U.S. Patent No. 4,444,933, “Columbus”). Claims 6 and 7 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac and Fierro***

Claims 8-11, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Fierro (International Patent Publication No. WO 01/45589, “Fierro”). Claims 8-11, 19, and 20 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac and Tihon***

Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Tihon (U.S. Patent No. 6,042,536, “Tihon”). Claims 12 and 13 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac and Scetbon***

Claims 17 and 23 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Scetbon (U.S. Patent No. 6,478,727, “Scetbon”). Claims 17 and 23 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac, Gellman, and Cheroudi***

Claims 21 and 22 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Kovac in view of Gellman (U.S. Patent No. 6,042,534, “Gellmann”) and Cheroudi ((1988) *J. Biomed. Res.*, 22(6):459-473). Claims 21 and 22 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

***Kovac and Kammerer***

Claims 28-31 stand rejected under 35 U.S.C. 103(a) as being allegedly obvious over Kovac in view of Kammerer (U.S. Patent Application Publication No. 2002/0077526, "Kammerer"). Claims 28-31 have been canceled, thereby obviating the rejection. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

**CONCLUSION**

Applicant believes the claims are now in condition for allowance. The Examiner is invited to telephone the undersigned to discuss any outstanding issues.

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Respectfully submitted,

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APPLICANT: Browning	CONFIRMATION NO.: 1575
APPLICATION NO.: 10/510,488	GROUP NO.: 4185
FILING DATE: March 28, 2005	EXAMINER: Burk, Catherine E.
TITLE: Apparatus and Method for Treating Female Urinary Incontinence	

## TERMINAL DISCLAIMER

I, James Browning, state that I am a representative authorized to sign on behalf of Gyne Ideas Limited, identified below as the assignee of the entire right, title, and interest in and to the above-identified patent application, U.S. Application No. 10/510,488 (the “488 application”). I have reviewed all the evidentiary documents accompanying or referred to in the instant Terminal Disclaimer and certify that, to the best of my knowledge and belief, that the entire right, title, and interest to the above-identified application is in the name of Gyne Ideas Limited.

Gyne Ideas Limited of 1 Bell Leys, Wingrave, Buckinghamshire, United Kingdom, HP22 4QD, is the assignee of the entire right, title, and interest in and to the '488 application, by virtue of the Assignment from the inventor of this application to Gyne Ideas Limited, recorded in the United States Patent and Trademark Office on September 20, 2005, at Reel No. 016821, Frame No. 0676.

Gyne Ideas Limited hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the ‘488 application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,960,160, (the “‘160 patent”), issued November 1, 2005, as the term of said ‘160 patent is defined in 35 U.S.C. 154 and 173, and as the term of said ‘160 patent is presently shortened by any terminal disclaimer. Gyne Ideas Limited hereby agrees that any patent so granted on the ‘488 application shall be enforceable only for and during such period that the legal title to any patent so granted on the ‘488 application shall be the same as the legal title to U.S. Patent No. 6,960,160. This agreement runs with any patent granted on the ‘488 application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, Gyne Ideas Limited does not disclaim the terminal part of the term of any patent granted on the '488 application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the '160 patent, "as the term of said '160 patent is presently shortened by any terminal disclaimer," in the event that the '160 patent later expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutory disclaimed in whole, or terminally disclaimed under 37 C.F.R. 1.321(a); has all claims canceled by a re-examination certificate; is reissued; or is in any manner terminated prior to expiration of its full statutory term as presently shortened by any terminal disclaimer, if any, except for the separation of legal title stated above.

Gyne Ideas Limited is the owner of the entire right, title and interest in U.S. Patent No. 6,960,160, issued November 1, 2005, by virtue of an assignment recorded in the U.S. Patent and Trademark Office on April 11, 2003, at Reel No. 014188, Frame No. 0696.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Gyne Ideas Limited

By: DRAFT

Title: \_\_\_\_\_

Date: \_\_\_\_\_